

## Appendix 4

### Clozapine Management Services

#### Conditions for Clozapine Management

Pharmacies may be separately reimbursed for clozapine management services when all of the following conditions are met:

- A physician prescribes the clozapine management services in writing if any of the components of clozapine management are provided by individuals who are not under the direct, on-site supervision of a physician. Although separate prescriptions are not required for clozapine tablets and clozapine management, the clozapine management service must be identified as a separately prescribed service from the drug itself.
- The recipient is currently taking or has taken clozapine tablets within the past four weeks.
- The recipient resides in a community-based setting (excludes hospitals and nursing facilities).
- The physician or qualified staff person has provided the components of clozapine management as described below.

Clozapine is appropriate for recipients with an *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) code diagnosis between 295.10 and 295.95 and who have a documented history of failure of at least two psychotropic drugs. Lithium Carbonate may not be one of the two failed drugs. Reasons for the failure may include:

- No improvement in functioning level.
- Continuation of positive symptoms (hallucinations or delusions).
- Severe side effects.
- Tardive dyskinesia/dystonia.

#### Components of Clozapine Management

The following components are part of the clozapine management service (regardless of which of the three clozapine management procedure codes is billed) and must be provided, as needed, by the physician or by a qualified professional under the general supervision of the physician:

1. Ensure that the recipient has the required weekly or biweekly white blood count testing. Recipients must have a blood sample drawn for white blood cell count testing before initiation of treatment with clozapine and must have subsequent white blood cell counts done weekly for the first six months of clozapine therapy.

If a recipient has been on clozapine therapy for six months of continuous treatment and if the weekly white blood cell counts remain stable (greater than or equal to 3,000/mm<sup>3</sup>) during the period, the frequency of white blood cell count monitoring may be reduced to once every two weeks. For these recipients, further weekly white blood cell counts require justification of medical necessity. *Recipients who have their clozapine dispensed every week but have their blood drawn for white blood cell counts every two weeks qualify for biweekly, not weekly, clozapine management services.*

For recipients who have a break in therapy, white blood cell counts must be taken at a frequency in accordance with the rules set forth in the “black box” warning of the manufacturer’s package insert.

The provider may draw the blood or transport the recipient to a clinic, hospital, or laboratory to have the blood drawn, if necessary. The provider may travel to the recipient’s residence or other places in the community where the recipient is available to perform this service, if necessary. The provider’s transportation to and from the recipient’s home or other community location to carry out any of the required services listed here is considered part of the capitated weekly or biweekly payment for clozapine management and is not separately reimbursable. The blood test is separately reimbursable for a Medicaid-certified laboratory.

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2. Obtain the blood test results in a timely fashion.
3. Ensure that abnormal blood test results are reported in a timely fashion to the provider dispensing the recipient's clozapine.
4. Ensure that the recipient receives medications as scheduled and that the recipient stops taking medication when a blood test is abnormal, if this decision is made, and receives any physician-prescribed follow-up care to ensure that the recipient's physical and mental well-being is maintained.
5. Make arrangements for the transition and coordination of the use of clozapine tablets and clozapine management services between different care locations.
6. Monitor the recipient's mental status according to the care plan. The physician is responsible for ensuring that all individuals having direct contact with the recipient in providing clozapine management services have sufficient training and education. These individuals must be able to recognize the signs and symptoms of mental illness and side effects from drugs used to treat mental illness and to recognize when changes in the recipient's level of functioning need to be reported to a physician or registered nurse.
7. Keep records as described below.

### Recordkeeping Requirements for Clozapine Management

The provider must have a unique record for each recipient for whom clozapine management is being provided. This record may be a part of a larger record which is also used for other services if the provider is also providing other services to the recipient. However, the clozapine management records must be clearly identified as such and must contain the following:

- A face sheet identifying the recipient including the following information:
    - ✓ Recipient's Medicaid identification number.
    - ✓ Recipient's name.
    - ✓ Recipient's current address.
    - ✓ Name, address, and telephone number of the primary medical provider (if different than the prescribing physician).
    - ✓ Name, address, and telephone number of the dispensing provider from whom the recipient is receiving clozapine.
    - ✓ Address and telephone number of other locations at which the recipient may be receiving a blood draw and at which the recipient may be located on a regular basis.
  - A care plan indicating the manner in which the provider ensures that the covered services are provided (e.g., plan indicates where and when blood will be drawn, whether the recipient will pick up medications at the pharmacy or whether they will be delivered by the provider). The plan should also specify signs or symptoms that might be associated with medical conditions resulting from side effects of the drug or related to the recipient's mental illness which should be reported to a qualified medical professional.
- The plan should indicate the health care professionals to whom oversight of the clozapine management services has been delegated and indicate how often they will be seeing the recipient. The plan should be reviewed every six months during the first year of clozapine use. Reviews may be reduced to once per year after the first year of use if the recipient is stable, as documented in the record.
- Copies of physician's prescriptions for clozapine and clozapine management.
  - Copies of laboratory results of white blood cell counts.
  - Signed and dated notes documenting all clozapine management services. Indicate date of all blood draws as well as who performed the blood draws. If the provider had to travel to provide services, indicate the travel time. Document services provided to ensure that the recipient received medically necessary care following an abnormal white blood cell count.

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Physicians and pharmacies providing clozapine management services must be extremely careful not to double bill Wisconsin Medicaid for services. This may happen when the physician provides clozapine management services as well as other Medicaid-allowable physician services during the same encounter. In these cases, the physician must document the amount of time that was spent on the other physician service separate from the time spent on clozapine management. Regular psychiatric medication management is not considered a part of the clozapine management services and may be billed separately.

### **Noncovered Clozapine Management Services**

Wisconsin Medicaid does not cover the following as clozapine management services:

- Clozapine management for a recipient not receiving clozapine, except for the first four weeks after discontinuation of the drug.
- Clozapine management for recipients residing in a nursing facility or hospital on the date of service.
- Care coordination, medical services, or provider transportation not related to the recipient's use of clozapine.

### **Related Services That are Reimbursed Separately from Clozapine Management**

**White Blood Cell Count** - The white blood cell count must be performed and billed by a Medicaid-certified laboratory to receive Wisconsin Medicaid reimbursement.

**Recipient Transportation** - Recipient transportation to a physician's office or pharmacy is reimbursed in accordance with HFS 107.23, Wis. Admin. Code. Such transportation, when provided by a specialized medical vehicle, is not covered unless the recipient has a disability. Recipient transportation by common carrier must be approved and paid for by the county agency responsible for Medicaid transportation services.

### **Billing for Clozapine Management**

Refer to the Claims Submission section of this handbook for information on billing for clozapine management.